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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,743	07/03/2001	Krassen Dimitrov	P-IS 4548	3666

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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05/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/898,743

Applicant(s)

DIMITROV, KRASSEN

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-178 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-178 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/7/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on February 07, 2007 has been entered.

Status of the Application

2. Claims 90-178 are pending. All amendments and arguments have been thoroughly reviewed and deemed persuasive in view of arguments and the reasons that follow.

3. The Information Disclosure Statement filed on February 07, 2007 has been considered.

Informalities

4. The following informalities are noted:

(i) the dependent claims 95-178 lack reference to a claim upon which they depend.

Sequence Rules and Objection to the Specification

5. The specification is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825. The instant application recites sequences that are not identified by SEQ ID No. (see at least page 36, and 53) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Examiner also notes that the application contains no sequence listing either in the form of a paper copy or in a computer readable form.

Appropriate correction is required.

Claim Objections

6. Claims 123, 130, 131 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 123, 130, 131 dependent on multiple claims. See MPEP § 608.01(n). Amendment to recite dependency in alterantive form is suggested.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 90-178 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem et al. (US 6, 261, 779) in view of Tanke et al. (European J Human Genetics, Vol. 7, page 2-11, 1999):

Barbera-Guillem et al. teach a composition and a kit of claims 90-94, 151-152, 157-177 comprising a diverse population of unique labels comprising plurality of distinguishable labels (quantum dots having two or more unique labels) each unique label comprises a molecule (nanocrystal) said molecule comprising plurality of genedigits (polynucleotide strands (primary quantam dots), each genedigit being a predetermined sequence wherein genedigit is attached to an anti-genedigit (secondary quantum dots comprising complementary sequence to a polynucleotide on the primary quantum dot (see at least col. 2, line 13-46, col. 22, line 4-67, col. 23, line 1-33, col. 24, line 1-25).

With regard to claim 90, Barbera-Guillem et al. teach that said population is in solution (see at least col. 10, line 3-33).

With regard to claim 95-120, 158, 166-167, Barbera-Guillem et al. teach that each genedigit is DNA comprising target specific nucleic acid sequence (see at least col.14, line 13-67).

With regard to claims 92, 96, 99, 106, 113-120, 123, Barbera-Guillem et al. teach that the molecule is attached to a target molecule noncovalently via hybridization (see at least col. 2, line 66-67, col. 3, line 1-49).

With regard to claim 92, 99, Barbera-Guillem et al. teach that said population comprises bridging nucleic acid (see at least col. 3, line 35-42, Fig.7, col. 5, line 63-67, col. 6, line 1-14);

With regard to claim 124-127, Barbera-Guillem et al. teach that the diverse population comprises genedigits with two or more different sequences (see at least col. 22, line 4-67, col. 23, line 1-33, col. 24, line 1-25).

With regard to claim 90-129, 136-137, 153-155, 150-160, Barbera-Guillem et al. teach that said population of molecules comprise label monomers and at least one label monomer comprises fluorescent label (see at least col. 22, line 4-67, col. 23, line 1-33, col. 24, line 1-25).

With regard to claim 130, Barbera-Guillem et al. teach that said unique labels comprise mixture of two or more different labels (see at least col. 22, line 4-60).

With regard to claim 132, 151, 161, Barbera-Guillem et al. teach said labels comprise quantum dot (see at least col. 2, line 13-46, col. 22, line 4-67, col. 23, line 1-33, col. 24, line 1-25).

With regard to claim 133-135, 162-164, Barbera-Guillem et al. teach that diverse population further comprises a specifier, a dendrimer of a fork-like or comb-like (see at least col. 2, line 66-67, col. 3, line 1-49, col. 8, line 61-66).

With regard to claims 135-141, 156, 178, Barbera-Guillem et al. teach that said target is attached to a chip or microarray (solid support) (see col. 2, line 66-67, col. 3, line 1-49).

With regard to claim 158, Barbera-Guillem et al. teach that said genedigit comprises a repeated core element (see at least col. 14, line 39-43).

Although Barbera-Guillem et al. teach two or more unique label monomers, Barbera-Guillem et al. did not specifically teach a diverse population of labels comprising thirty or more labels or label combinations.

Tanke et al. teach multi-color fluorescence in-situ hybridization probes, wherein Tanke et al. teach that the combinatorial ratio labeling result in unique labels with different distinguishable colors giving more than 30 unique labels or 48, 96 or more distinguishable colors or labels (see page 3, col. 2, paragraph 1, paragraph 1-2 under Materials and methods, col. 1, paragraph 3 under introduction).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the diverse population of quantum dots comprising genedigits and anti genedigits as taught by Barbera-Guillem et al. with an inclusion of combinatorial ratio labeling as taught by Tanke et al. to develop a sensitive and improved population of molecules with distinct labels. An ordinary artisan would have had a reasonable expectation of success that such modification of diverse population of quantum dots taught by Barbera-Guillem et al. in a manner as taught by Tanke et al. would result in a large population of

unique labels because Tanke et al. explicitly taught that combinatorial labeling or binary ratio labeling provides the number of recognizable targets (n) using (k) different fluorophores result in $n = 2^k - 1$ colors that utilizes no major instruments to analyse other than a good digital fluorescence microscope (see page 3, col. 1 paragraph 3, col. 2, paragraph 1, paragraphs 1-2 under materials and methods section) and such modification of the method is considered obvious over the cited prior art.

Response to arguments:

6. With regard to the rejections under 35 USC 103(a) as being unpatentable over Oprandy et al., in view of Segev, Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the persuasive arguments regarding "unique labels.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Suryaprabha Chunduru
SURYAPRABHA CHUNDURU 5/9/07
PRIMARY EXAMINER